

## BEST AVAILABLE COPY

Attorney Docket No.: DEX-0117  
Inventors: Salceda et al.  
Serial No.: 09/721,183  
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In the Claims:

Please amend the claims as follows:

3. (amended) A method for diagnosing the presence of breast cancer in a patient comprising:

(a) determining levels of Breast Cancer Specific Gene (BCSG) polynucleotide in cells, tissues or bodily fluids in a patient; and

C1 (b) comparing the determined levels of BCSG polynucleotide with levels of BCSG polynucleotide in cells, tissues or bodily fluids from a normal human control, wherein an increase in determined levels of BCSG polynucleotide in said patient versus normal human control is associated with the presence of breast cancer and wherein the BCSG polynucleotide comprises SEQ ID NO:1, 2, 3, 4, 5, 18 or 20 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 1, 2, 3, 4, 5, 18 or 20.

4. (amended) A method of diagnosing metastases of breast cancer in a patient comprising:

(a) identifying a patient having breast cancer that is not known to have metastasized;

(b) determining Breast Cancer Specific Gene (BCSG)

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polynucleotide levels in cells, tissues, or bodily fluid from said patient; and

(c) comparing the determined BCSG polynucleotide levels with levels of BCSG polynucleotide in cells, tissue, or bodily fluid of a normal human control, wherein an increase in determined BCSG polynucleotide levels in the patient versus the normal human control is associated with breast cancer which has metastasized and wherein the BCSG polynucleotide comprises SEQ ID NO:1, 2, 3, 4, 5, 18 or 20 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 1, 2, 3, 4, 5, 18 or 20.

C2 5. (amended) A method of staging breast cancer in a patient having breast cancer comprising:

(a) identifying a patient having breast cancer;  
(b) determining Breast Cancer Specific Gene (BCSG) polynucleotide levels in a sample of cells, tissue, or bodily fluid from said patient; and

(c) comparing determined BCSG polynucleotide levels with levels of BCSG polynucleotide in cells, tissues, or bodily fluid of a normal human control, wherein an increase in determined BCSG polynucleotide levels in said patient versus the normal human control is associated with breast cancer which is

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progressing and a decrease in the determined BCSG polynucleotide levels is associated with breast cancer which is regressing or in remission and wherein the BCSG polynucleotide comprises SEQ ID NO:1, 2, 3, 4, 5, 18 or 20 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 1, 2, 3, 4, 5, 18 or 20.

6. (amended) A method of monitoring breast cancer in a patient for the onset of metastasis comprising:

C3 (a) identifying a patient having breast cancer that is not known to have metastasized;

(b) periodically determining levels of Breast Cancer Specific Gene (BCSG) polynucleotide in samples of cells, tissues, or bodily fluid from said patient; and

(c) comparing the periodically determined BCSG polynucleotide levels with levels of BCSG polynucleotide in cells, tissues, or bodily fluid of a normal human control, wherein an increase in any one of the periodically determined BCSG polynucleotide levels in the patient versus the normal human control is associated with breast cancer which has metastasized and wherein the BCSG polynucleotide comprises SEQ ID NO:1, 2, 3, 4, 5, 18 or 20 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 1,

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2, 3, 4, 5, 18 or 20.

7. (amended) A method of monitoring a change in stage of breast cancer in a patient comprising:

(a) identifying a patient having breast cancer;

(b) periodically determining levels of Breast Cancer Specific Genes (BCSG) polynucleotide in cells, tissues, or bodily fluid from said patient; and

C4 (c) comparing the periodically determined BCSG polynucleotide levels with levels of BCSG polynucleotide in cells, tissues, or bodily fluid of a normal human control, wherein an increase in any one of the periodically determined BCSG polynucleotide levels in the patient versus the normal human control is associated with breast cancer which is progressing in stage and a decrease is associated with breast cancer which is regressing in stage or in remission and wherein the BCSG polynucleotide comprises SEQ ID NO:1, 2, 3, 4, 5, 18 or 20 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 1, 2, 3, 4, 5, 18 or 20.

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REMARKS

Claims 3-7 and 18-37 are pending in the instant application.  
The Office Action Summary Sheet indicates claims 3-5 and 18-37 to